

CLAIMS

We claim:

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1. A method for the sterile joining of two or more pre-sterilized components comprising the steps of:
 - a. sterilizing an end of each component to be joined together within an active sterile field;
 - b. preparing the end of each component to be joined while exposed to the active sterile field; and
 - c. joining the prepared ends together while exposed to the active sterile field.
 - 10 2. The method of claim 1, wherein the step of preparing includes the step of opening an end of each component to be joined.
 - 15 3. The method of claim 1, wherein the step of sterilizing comprises the steps of:
 - a. creating an electron beam field to produce an active sterile field; and
 - b. positioning the ends within the electron beam field.
 - 20 4. The method of claim 3, wherein the step of creating an electron beam field comprises the step of establishing the field at a voltage of less than 300 KeV.
 5. The method of claim 4, wherein the electron beam field is established within the range of from about 30 to about 300 KeV.
 - 25 6. The method of claim 4, wherein the electron beam field is established within the range of from about 30 to about 100 KeV.
 - 30 7. The method of claim 6, wherein the electron beam field is established at about 60 KeV.

8. The method of claim 1, wherein the step of sterilizing comprises the steps of:
- creating a chemical vapor atmosphere to produce an active sterile field; and
 - positioning the ends within the chemical vapor atmosphere.

- 5 9. The method of claim 8, wherein the step of creating a chemical vapor atmosphere comprises the step of selecting a suitable chemical compound from the group comprising hydrogen peroxide, peracetic acid, and chlorine dioxide.

- 10 10. The method of claim 1, wherein the step of sterilizing comprises the steps of:
- pulsing a high-energy light with a large ultraviolet component to produce an active sterile field; and
 - positioning the ends within the pulsed high-energy light.

- 15 11. The method of claim 1, wherein the step of sterilizing comprises the steps of:
- creating a plasma atmosphere to produce an active sterile field; and
 - positioning the terminal sealed ends within the plasma atmosphere.

- 20 12. The method of claim 11, wherein the step of creating a plasma atmosphere is achieved using ozone.

13. The method of claim 1, wherein the steps of sterilizing, preparing, and joining are automated.

- 25 14. The method of claim 2, wherein the step of joining comprises the steps of:
- inserting an opened end of one component into the opened end of another component to create overlapping sections; and
 - bonding the overlapping sections together.

- 30 15. The method of claim 2, wherein the step of joining comprises the steps of:
- abutting the opened end of one component with the opened end of another component; and
 - welding the abutting ends together.

16. The method of claim 1, wherein the step of preparing includes the step of severing at least one component end.

17. The method of claim 1, wherein the step of preparing includes the step of uncapping at least one component end.

18. A method for sterile filling a pre-sterilized container having a filling port with a bulk sterile fluid comprising the steps of:

- a. establishing an active sterile field;
- b. introducing the filling port of the pre-sterilized container into the active sterile field;
- c. transferring an aliquot of the bulk sterile fluid from a supply container to the pre-sterilized container through the filling port; and
- d. removing the filling port of the pre-sterilized container from the active sterile field.

19. The method of claim 18, further comprising the step of sealing the filling port of the pre-sterilized container after transferring an aliquot of the bulk sterile fluid.

20. The method of claim 18, wherein the step of transferring comprises the steps of:

- a. exposing a dispensing end attached to a supply of the bulk sterile fluid into the active sterile field;
- b. breaching the sealed filling port with the dispensing end;
- c. delivering the bulk sterile fluid to the pre-sterilized container; and
- d. sealing the breached filling port.

21. The method of claim 18, wherein the steps of introducing, transferring, and removing are automated.

22. The method of claim 18, wherein the step of establishing comprises the step of creating an electron beam field with a voltage of less than 300 Kev to produce an active sterile field.

23. The method of claim 22, wherein the electron beam field is established within the range of from about 30 to about 300 KeV.
24. The method of claim 22, wherein the electron beam field is established within the range of from about 30 to about 100 KeV.
25. The method of claim 24, wherein the electron beam field is established at about 60 KeV.
26. The method of claim 18, wherein the step of establishing comprises the step of creating a plasma atmosphere to produce an active sterile field.
27. The method of claim 18, wherein the step of establishing comprises the step of using a high energy pulsed light with a large ultraviolet component to produce an active sterile field.
28. The method of claim 18, wherein the step of establishing comprises the step of creating a chemical vapor atmosphere to produce an active sterile field.
29. The method of claim 18, further comprising the step of preventing the bulk sterile fluid from being affected by the active sterile field.
30. The method of claim 18, further comprising the step of repeating steps (b) through (d) with another pre-sterilized container having a filling port.
31. The method of claim 30, further comprising the step of maintaining the active sterile field between consecutive pre-sterilized containers.
32. The method of claim 20, further comprising the step or repeating the steps of introducing the filling port, transferring an aliquot, and removing the filling port, using another pre-sterilized container having a filling port.

33. The method of claim 32, further comprising the step of maintaining the sterility of the dispensing end between consecutive pre-sterilized containers.

5 34. A method for the sterile assembly of two or more pre-sterilized components together comprising the steps of:

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- a. preparing at least one end of each component for assembly;
 - b. sterilizing the prepared ends of each component to be assembled together within an active sterile field;
 - c. bringing the prepared ends into contact with each other while in the active sterile field; and
 - d. assembling the prepared ends together while in the active sterile field.

10 35. The method of claim 34, wherein the step of preparing the ends includes the step of removing a cap from at least one of the ends.

15 36. The method of claim 34, wherein the step of sterilizing comprises the steps of:

- a. creating an electron beam field to produce an active sterile field; and
- b. positioning the ends within the electron beam field.

20 37. The method of claim 36, wherein the step of creating an electron beam field comprises the step of establishing the field at a voltage of no more than 300 Kev.

25 38. The method of claim 37, wherein the electron beam field is established within the range of from about 30 to about 300 KeV.

30 39. The method of claim 38, wherein the electron beam field is established within the range of from about 30 to about 100 KeV.

40. The method of claim 39, wherein the electron beam field is established at about 60 KeV.

41. The method of claim 34, wherein the step of sterilizing comprises the steps of:
- a. creating a chemical vapor atmosphere to produce an active sterile field; and
 - b. positioning the ends within the chemical vapor atmosphere.

- 5 42. The method of claim 38, wherein the step of creating a chemical vapor atmosphere comprises the step of selecting a suitable chemical compound from the group comprising hydrogen peroxide, peracetic acid, and chlorine dioxide.

- 10 43. The method of claim 34, wherein the step of sterilizing comprises the steps of:
- a. pulsing a high-energy light with a large ultraviolet component to produce an active sterile field; and
 - b. positioning the ends within the pulsed high-energy light.

- 15 44. The method of claim 34, wherein the step of sterilizing comprises the steps of:
- a. creating a plasma atmosphere to produce an active sterile field; and
 - b. positioning the ends within the plasma atmosphere.

- 20 45. The method of claim 41, wherein the step of creating a plasma atmosphere is achieved using ozone.

- 25 46. A system for effecting the sterile joining of at least two pre-sterilized components together comprising:
- a. an active sterile field for encompassing at least one end of each component to be joined together;
 - b. a surface for supporting the ends of the pre-sterilized components within the active sterile field;
 - c. a mechanism which opens the ends of the pre-sterilized components while supported by the surface in the active sterile field;
 - d. a mechanism which brings the opened ends into aligned contact with each other while in the active sterile field; and
 - e. a sealing device for bonding the opened ends together.
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47. The system of claim 46, wherein the active sterile field is created by a low voltage electron beam instrument.

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48. The system of claim 47, wherein the low voltage electron beam instrument operates within the range of from about 30 KeV to about 300 KeV.

49. The system of claim 47, wherein the low voltage electron beam instrument operates within the range of from about 60 KeV to about 100 KeV.

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50. The system of claim 46, wherein the active sterile field is created by a chemical vapor atmosphere.

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51. The system of claim 50, wherein the chemical vapor atmosphere is created by a chemical selected from the group of chemicals including hydrogen peroxide, peracetic acid, and chlorine dioxide.

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52. The system of claim 46, wherein the active sterile field is created by a pulsed high-energy light source having a large ultraviolet component.

53. The system of claim 46, wherein the active sterile field is created by a plasma atmosphere.

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54. The system of claim 46, wherein the mechanism which brings the opened ends into contact comprises at least one mechanical actuator.

55. The system of claim 54, wherein the at least one mechanical actuator is automated.

56. The system of claim 46, wherein the surface for supporting is automated.

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